REMARKS

Status Summary

Claims 1-33 are pending in the present application. Claims 1-33 presently stand rejected. Claims 34-35 were previously canceled. With this amendment, claims 1, 6, 10, 14, 16, 22, 24, 29 and 31 have been amended. Claims 2, 5, 7, 8, 23, and 30 have been canceled. New claims 36-42 have been added. Reconsideration of the application is respectfully requested.

Claim Objections

Claim 19 stands objected to as being of improper dependent form for failing to further limit the subject matter of the previous claim. Claim 29 stands objected to as being indefinite due to the phrase "rack-like."

Applicants respectfully submit that claim 19 does further limit claim 18 by identifying what drug is contained in the container, since both the drug and container are claimed in claim 18. Claim 19 does not merely recite the intended use of the drug but actually identifies a type or class of drug. Using the terms "for treatment or prophylaxis of a **respiratory disease or disorder**" to modify "drug composition" in claim 19 limits what the drug composition of claim 18 can be. Therefore, claim 19 does further limit the subject matter of the previous claim.

Claim 29 has been amended to address the Examiner's objection. In particular, the phrase "rack-like" has been changed to "rack."

Accordingly, applicants respectfully submit that the objections to claims 19 and 29 should be withdrawn.

Claim Rejections – 35 U.S.C. § 102

Claims 1-5, 7-11, 13-23, 25-27 and 29-33 stand rejected by the Examiner under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,826,571 to Casper, et al. (hereinafter "Casper"). Claims 1-8, 13-20, 22-24 and 30-33 stand rejected by the Examiner under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,273,084 to Frid (hereinafter "Frid"). These rejections are respectfully traversed.

Independent claim 1 recites a drug delivery device for delivering to a patient a drug composition from a container which contains the drug composition. The container is adapted to be placed in a dispensing mode thereof on application of an actuating condition thereto which is a movement of a first part of the container relative to a second part of the container. Claim 1 also recites a dispensing unit adapted to receive the container. Claim 1 as amended recites that the dispensing unit has an actuating mechanism hand-operable to apply the actuating condition to the container, and an outlet through which the drug composition is dispensable from the device. The actuating mechanism is configured to hold the second part of the container stationary and to allow the first part to move relative thereto for dispensing the drug composition from the container. Claim 1 also recites a casing unit for the dispensing unit. Claim 1 has been amended to recite that the casing unit is configured be movable between a closed state in which the casing unit covers the outlet, and more generally is configured to enclose the dispensing unit with the container received therein, and an open state in which the casing unit uncovers the outlet.

Claim 1 further recites that the dispensing and casing units have securing features for fixedly securing the units together. Claim 1 has been amended to recite that the actuating mechanism is hand-operable to apply the actuating condition to the container when the dispensing unit is fixedly secured to the casing unit with the casing unit in the open state, but not the closed state. Claim 1 has also been amended to recite that the securing features are adapted to releasably secure the casing unit and the dispensing unit together so that the casing unit is removable from the dispensing unit. Claim 1 has further been amended to recite that the dispensing unit is hand-operable to apply the actuating condition to the container when the dispensing unit is independent from the casing unit.

Independent claim 22 recites a method of manufacturing a hand-operated drug delivery device for delivery of a drug formulated in a drug container which is adapted to be placed in a dispensing mode on application of an actuating condition thereto which is a movement of a first part of the container relative to a second part of the container. The method of claim 22 recites providing a dispensing unit for receiving the container with the dispensing unit having an actuating mechanism hand-operable to apply the actuating condition to the container of a movement of a first part of the container relative to a second part of the container and an outlet through which the drug formulation is dispensed on application of the actuating condition to the container. The actuating mechanism is configured to hold the second part of the container stationary and to allow the first part to move relative thereto for dispensing the drug composition from the container. The method of claim 22 also recites separately providing a casing unit

adapted to fixedly hold the dispensing unit such that the drug is dispensable from the container by the dispensing unit when held by the casing unit. The casing unit is configured to be movable between a closed state in which the casing unit covers the outlet, and more generally is configured to enclose the dispensing unit with the container received therein, and an open state in which the casing unit uncovers the outlet.

Claim 22 further recites that the dispensing and casing units have securing features for fixedly securing the units together. Claim 22 has been amended to recite that the actuating mechanism is hand-operable to apply the actuating condition to the container when the dispensing unit is fixedly secured to the casing unit with the casing unit in the open state, but not the closed state. Claim 22 has also been amended to recite that the securing features are adapted to releasably secure the casing unit and the dispensing unit together so that the casing unit is removable from the dispensing unit. Claim 22 has further been amended to recite that the dispensing unit is hand-operable to apply the actuating condition to the container when the dispensing unit is independent from the casing unit.

Applicants respectfully submit that Casper does not anticipate independent claims 1 and 22 or the claims that depend therefrom as Casper does not disclose all the features of independent claims 1 and 22. For example, Casper does not disclose a drug delivery device with a dispensing unit that is configured to be hand-operated when independent from or fixedly secured to the casing unit.

Casper discloses an inhalation device for use with pressurized metered dose inhalers ("MDIs"). The device includes a mechanical mechanism for applying the force required to discharge the MDI, a breath-activated trigger for activating this mechanical mechanism, an auto-return mechanism for insuring recovery of the aerosol canister from the fired position and a dose counter for counting the doses dispensed or available. Arming of the device is achieved by removing the protective mouthpiece cover/dust cap. Activation of the MDI is set to occur at a point subsequent to the beginning of inhalation. Casper states that it is an object of the invention therein "to provide an inhalation device for use with MDIs which includes a mechanical mechanism for applying the force required to actuate an MDI at a preset patient inspiration flow rate." (See Casper col. 4, lines 35-38.)

Referring to Figures 1 and 2, Casper discloses a breath-activated inhalation device, generally designated **10**, for mechanically actuating and restoring, to the "resting" position, an aerosol canister **12** of an MDI, generally designated **14**, under the action of a patient's inspiratory flow, thereby alleviating the difficulty most patients experience in coordinating inspiration with inhalation and manually actuating a MDI to achieve optimal deposition of medication in the lungs. MDI **14**, consisting of medicament-containing aerosol canister **12** and its associated actuator **16**, is incorporated directly into inhalation device **10** by the patient and may be used with a variety of different MDI products. Inhalation device **10** can include access panel **17** which can be used to insert and remove MDI **14** from inhalation device **10**. (See Casper col. 5, lines 14-33.)

"Arming" of the mechanical actuating mechanism may be initiated by a user by opening a mouthpiece cover or protective dust cap **18** which is operatively connected to power spring **20** by a latching mechanism. As shown in Figure 2, the latching mechanism can comprise arm **22** and receiving member **24** for operatively receiving arm **22** and which is connected to power spring **20**. Opening dust cap **18** latches and stretches power spring **20**, the distal end of which is connected to an actuating platform **26** that is latched in the fixed position by a breath or inspiration-activated catch/release mechanism **28**. Activating platform **26** is further connected to a weaker return spring **30**, the distal end of which is affixed to the housing of device **10**. When a user inhales and reaches a preset inspiration flow rate, breath-activated catch/release mechanism **28** releases actuating platform **26** and the force stored in "stretched" power spring **20** pulls actuating platform **26** downward, depressing and venting aerosol canister **12** housed in device **10** and releasing medicant contained therein as an aerosol mist. (See Casper col. 5, lines 34-53.)

Thus, it is clear that Casper discloses only a breath-operated inhaler. The catch/release mechanism is completely enclosed within the device. Casper provides no manner in which to trigger the release of the medicant. In fact, it is an objective of the invention in Casper to provide to provide a mechanical mechanism for applying the force required to actuate an MDI at preset inspiration flow rate. Therefore, Casper does not disclose a dispensing unit that is configured to be hand-operated when independent from and fixedly secured to the casing unit. Rather, Casper discloses only breath

operated dispensing systems. Therefore, Casper does not disclose all the features of claims 1 and 22 of the present application.

Applicants respectfully submit that Frid also does not anticipate independent claims 1 and 22 or the claims that depend therefrom as Frid does not disclose all the features of independent claims 1 and 22. For example, Frid does not disclose, teach, or suggest a casing unit configured to enclose the dispensing unit with the container received therein when the casing unit is in a closed state.

Frid discloses an actuator for an inhaler for administering medicament by inhalation that includes a main body **1** defining a chamber **4** for receiving a canister **3** containing medicament, and including an outlet **11** through which medicament is delivered in use. (See Frid col. 2, lines 59-67.) The canister **3** in use is acted upon by the user for the delivery of medicament. A cover member **2** is rotatable in relation to the main body **1** between a first, closed position in which the outlet **11** is covered and a second, open position in which the outlet **11** is exposed. The cover member **2** includes a grip portion **33**, which includes a surface **33a**. (See Frid col. 3, lines 50-54.) The cover member **2** also includes two substantially parallel side members **23** which are spaced to engage about the side walls of the main body **1**, and an interconnecting member **24**, arcuate in shape, which interconnects the side members **23**. The side members **23** of the cover member **2** each include an opposed opening **25**, which openings **25** are arranged to locate on the respective projecting studs **18** on the side walls of the main body **1** and allow rotation of the cover member **2** in relation to the main body **1**. The side members **23** of the cover member **2** each also include an inwardly

projecting stud **27**, which studs **27** are adapted to locate in the first and second recesses **19**, **21** in the main body **1** in the closed and the open positions of the cover member **2**, respectively. (See Frid col. 3, lines 37-49.)

In use, from the closed position as shown in Figure 2 of Frid, the user rotates the cover member **2** relative to the main body **1**, in the illustrated orientation in the clockwise manner. At a position near the open position of the cover member **2**, the surface **33a** of the grip portion **33** of the cover member **2** contacts the guiding surface **16b** of the projecting lip **16** of the main body **1**. With continued rotation of the cover member **2**, the surface **33a** of the grip portion **33** of the cover member **2** rides up the guiding surface **16b** of the projecting lip **16** of the main body **1** and becomes progressively more deformed. This deformation continues until the surface **33a** of the grip portion **33** of the cover member **2** passes over the guiding surface **16b** of the projecting lip **16** of the main body **1** and snaps back behind the locking surface **16a** of the projecting lip **16** of the main body **1** so as to lock the cover member **2** in the open position. In this position, the inhaler is ready for use. (See Frid col. 4, lines 1-16.)

The user then takes the inhaler in his/her hand and inserts the outlet **11** of the actuator into one of his/her nostrils, at the same time closing the other nostril. The user then holds his/her breath and actuates the canister **3** to administer a metered dose of medicament. After actuation of the canister **3**, the user withdraws the outlet **11** of the actuator from his/her nostril and repeats the procedure for the other nostril. The user then returns the cover member **2** to the closed position. From the open position of Figure 1 of Frid, the user deforms the cover member **2** slightly to move the surface **33a**

of the grip portion **33** of the cover member **2** radially outwardly sufficiently to allow the cover member **2** to be rotated, in the illustrated orientation in the anti-clockwise sense, and returned to the closed position. In the closed position the cover member **2** is held in place by location of the inwardly projecting studs **27** on the side members **23** of the cover member **2** in the respective ones of the first recesses **19** in the side walls of the main body **1**. (See Frid col. 4, lines 16-35.)

Frid does not disclose, teach, or suggest a casing unit configured to enclose the dispensing unit with the container received therein when the casing unit is in a closed state as recited in claim 1 and 22 of the present application. In order for the inhaler of Frid to operate with the cover member **2** rotating about the main body **1** in the manner disclosed therein, the cover member **2** cannot enclose the main body. The cover member **2** rotates around the main body **1** so that the main body **1** is only partially covered by the cover member **2** at any given time, whether in the open position or the closed position. In the closed position, the cover member **2** resides over the outlet **11** of the main body, but leaves the rear and lower end of the main body exposed. Therefore, Frid does not disclose, teach, or suggest all the features of claims 1 and 22 of the present application.

For the reasons outlined above, applicants respectfully submit that Casper and Frid fail to anticipate claims 1 and 22 of the present application. Claims 2-11 and 13-21 depend from claim 1. Claims 23-27 and 29-33 depend from claim 22. As such, applicants respectfully submit that the rejections of claims 1-11, 13-27 and 29-33 under 35 U.S.C. §102(b) should be withdrawn and the claims allowed at this time.

Claim Rejections – 35 U.S.C. § 103

Claims 9-12, 21, and 25-29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Frid in view of International Patent Publication No. WO 98/56444 to Rand et al. (hereinafter, "Rand"). These rejections are respectfully traversed.

Claims 9-12 and 21 depend from claim 1 and claims 25-29 depend from claim 22. As described above, Frid does not disclose, teach, or suggest all the features of claims 1 and 22. Rand does not overcome the significant shortcomings of Frid. Rand discloses a dispenser with a dose indicator therein. Rand does not disclose, teach, or suggest, for example, that a casing unit is configured to enclose the dispensing unit with the container received therein when the casing unit is in a closed state as recited in claims 1 and 22 of the present application.

Accordingly, since claims 9-12 and 21 depend from claim 1 and claims 25-29 depend from claim 22, applicants respectfully submit that these claims are not rendered obvious by the cited references. Therefore, applicants respectfully submit that the rejections of claims 9-12, 21 and 25-29 under 35 U.S.C. § 103(a) should be withdrawn and the claims allowed at this time.

New Claims

New claims 36-42 have been added by this amendment as indicated above. Claims 36-42 depend from claim 1. For the same reasons as described above, claims 36-42 are not anticipated or rendered obvious by Casper, Frid, or Rand, either alone or in combination. No new matter has been added.

CONCLUSION

In light of the above remarks, it is respectfully submitted that the present application is now in proper condition for allowance, and an early notice to such effect is earnestly solicited.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account No. **50-0426**.

Respectfully submitted,

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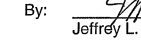
By: 

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